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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,837	08/16/2007	Ferdinand Koeckerling	72386	5339
23872 7590 11/23/2010 MCGLEW & TUTTLE, PC P.O. BOX 9227 SCARBOROUGH STATION SCARBOROUGH, NY 10510-9227				
EXAMINER				
MASHACK, MARK F				
ART UNIT		PAPER NUMBER		
3773				
MAIL DATE		DELIVERY MODE		
11/23/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/599,837

Applicant(s)

KOECKERLING ET AL.

Examiner

MARK MASHACK

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 9-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 9-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This office action is in response to a communication dated 9/9/2010. Claims 1-3, 9-22 are pending.

Response to Arguments

1. Applicant's arguments filed 9/9/2010 have been fully considered but they are not persuasive. Applicant argues that **Zotti** "does not teach or suggest that the combination of a plurality of annular mesh layers that are connected on one common side of a plurality of access slits by a plurality of connection points". Examiner disagrees. **Zotti** discloses of the meshes being joined only on the bottom side of the top layer and the top side of the bottom layer (Fig 2). Examiner asserts that this side is in common with both slits. **Zotti** discloses of the layers being joined with weld "along their contour... so as to obtain fully smooth polished, non sharp edges without ravel". The layers are mesh so that there are spaces between the fibers and the "sharp edges without ravel" would only be a problem if there were free ends of the fibers to unravel. Therefore Examiner asserts the welds are applied to individually spaced fibers of each of the mesh layers.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Claim 9** is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 9 requires the same group of connection points being positioned both along the inner and outer edge. The present application does not support that claim limitation.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. **Claims 1-3, 9**, are rejected under 35 U.S.C. 102(a) as being anticipated by **Zotti et al.** (“**Zotti**” **US 2003/0171823**).

Zotti discloses a two dimensional implant comprising: a first annular mesh layer comprising a central opening **2'** and an access slit **3'** extending through said central opening (Fig 5 and Paragraph 32); and a second mesh layer comprising a second annular opening **2''** and a second annular mesh layer access slit **3''** (Paragraph 32), the access slit of the first and second mesh layer are offset (Paragraph 56) and the central opening of each or aligned (Fig 1), wherein the first and second annular mesh layers are joined via connection points being formed in a form of seamed points or bonded

points (Paragraphs 41-42). **Regarding Claim 2**, the access slits can be offset by an angle of 180 degrees (Paragraph 56). **Regarding Claim 3**, the first and second layers have a congruent shape (Fig 1-4). **Regarding Claim 9**, the implant comprises points along the inner and outer edges (Paragraphs 41-42). **Regarding Claim 16, 18-19, 21**, the layers are mesh so that there are spaces between the fibers and the "sharp edges without ravel" would only be a problem if there were free ends of the fibers to unravel. Therefore Examiner asserts the welds are applied to individually spaced fibers of each of the mesh layers. **Regarding Claim 17, 20, 22**, "adjacent" is a broad term and either embodiment discussed meets the claim limitations (Paragraphs 41-42). **Regarding Claims 19, 21**, the first and second mesh are connected only on a common side (Fig 2).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. **Claim 10** is rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over **Zotti**.

Zotti discloses all of the claimed limitations except for the mesh layers being formed of a laser cut material.

However, laser cutting is a known method of forming the mesh layers.

Therefore, even if "the laser-cut mesh material" results in different structural characteristics of the end product than other molding methods, it still would have been *prima facie* obvious at the time the invention was made to use a "the laser-cut mesh material" material in since it is recognized as a useful technique for forming the mesh material.

9. **Claim 11-15** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Zotti** in view of **Willberg (DE 198 32 634)**.

Zotti discloses all of the claimed limitations except for the device having a coating containing metal. However, **Willberg** teaches of a similar hernia mesh with a coating containing metal (Col 4, Lines 17-28). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of **Zotti** with the coating in order to increase the adhesion factor (Col 4, Lines 17-28).

Regarding Claims 12-13, the coating contains titanium and a change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105

USPQ 237 (CCPA 1955). **Regarding Claim 14**, the access slits are arranged offset with respect to each other by an angle of 180 degrees (Paragraph 56).

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MARK MASHACK** whose telephone number is (571)270-3861. The examiner can normally be reached on Monday-Thursday 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Mashack/
Examiner, Art Unit 3773

/Darwin P. Erez/
Primary Examiner, Art Unit 3773